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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,429	10/31/2003	Sheldon B. Moberg	PF00419 Div	3250

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	**PAPER NUMBER**
3763	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,429	MOBERG, SHELDON B.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☒ Claim(s) *16-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-30) in the reply filed on 6/15/2007 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

Claims 16-30 are objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9-17, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Siposs et al. (4,435,173). Siposs discloses an external infusion device (10) for infusion of a fluid into a body from a reservoir (24) comprising a drive system (28,32,38) to operatively couple with the reservoir to infuse a fluid into a body, a housing (12) adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is at least partially contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to be carried by a user without significant restriction on mobility, electronic control circuitry (50) coupled to the drive system to control infusion of the fluid into the body, wherein the housing has at least one vent port (26,27) that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port (when the plunger is retracted, air and liquid are not permitted through the check valve 27 and when the plunder is depressed air is permitted into the housing to fill the barrel that was just filled with medication), wherein the at least one vent port further includes a hydrophobic material that permits the passage of air into and out of the

housing and inhibits the passage of liquids into the housing through the at least one vent port, wherein the hydrophobic material is pressed or molded into the device, wherein the device is water-proof and can deliver insulin, and wherein the vent port equalizes pressure.

Claims 1-2, 9-17, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Klatz et al. (5,709,654). Klatz discloses an external infusion device (20) for infusion of a fluid into a body from a reservoir (30) comprising a drive system (46) to operatively couple with the reservoir to infuse a fluid into a body, a housing (22) adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is at least partially contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to be carried by a user without significant restriction on mobility, electronic control circuitry (50) coupled to the drive system to control infusion of the fluid into the body, wherein the housing has at least one vent port (68,69) that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port, wherein the at least one vent port further includes a hydrophobic material that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port, wherein the hydrophobic material is pressed or molded into the device, wherein the device is water-proof and can deliver insulin, and wherein the vent port equalizes pressure.

Claims 1-2, 9-17, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Theeuwes et al. (5,151,093). Theeuwes discloses an external infusion device (20,30) for infusion of a fluid into a body from a reservoir (23) comprising a drive system (10) to operatively couple with the reservoir to infuse a fluid into a body, a housing (22) adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is at least partially contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to be carried by a user without significant restriction on mobility, electronic control circuitry (control circuitry which fills chamber 40 with liquid that controls the osmotic engine) coupled to the drive system to control infusion of the fluid into the body, wherein the housing has at least one vent port (34) that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port, wherein the at least one vent port further includes a hydrophobic material that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port, wherein the hydrophobic material is pressed or molded into the device, wherein the device is water-proof and can deliver insulin, and wherein the vent port equalizes pressure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-8 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siposs et al. (4,435,173), Klatz et al. (5,709,654), or Theeuwes et al. (5,151,093). The references disclose most of the limitations recited by the Applicant but fail to disclose various embodiments of the vent, such as a sheet or label. However, the Applicant has not disclosed that these embodiments work any better than the embodiments shown in the references. Therefore, these limitations are deemed to be matters of design choice that fail to patentably distinguish over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell

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